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| SER. NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
|---|---|---|---|
| 08/060,463 | 05/12/93 | CASKEY | C D5050C(C) |

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18N1/0601

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ART UNIT 1807 PAPER NUMBER 28

DATE MAILED: 06/01/94

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 5-12-93 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

**Part II SUMMARY OF ACTION**

1. ☒ Claims 1-20 are pending in the application.
   Of the above, claims 9-17 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-8 and 18-20 are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-20 are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

During a telephone conversation with Thomas Paul on 1/4/90, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8 (now claims 1-8 and 18-20) in the parent application, serial number 07/256,689, of which the instant application is a file-wrapper-continuation via application serial number 07/770,742. Affirmation of this election has been made by applicant in Paper No. 7, filed 8/16/90. This election is hereby assumed to be carried forward because this application is a file-wrapper-continuation as noted above of the parent applications. Claims 9-17 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Applicants' election of Group I Paper No. 7, filed 8/16/90 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

Applicants' Information Disclosure Statement, filed 9/15/92,

and arguments, filed 9/15/92, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The rejection based on NEW MATTER caused by the amendment which added the limitation to claim 1 cited as "all primers having similar melt characteristics" is reiterated and maintained from the previous office action. The Examiner agrees with applicants that the amended Table 1 (page 20) which adds melt temperature values is an inherent disclosure for hybridization between primers and their complements and is thus not NEW MATTER. This list however does not disclose the concept nor the requirement that primers must have similar melt temperature characteristics for the practice of the instantly claimed

methods. Therefore the similar melt temperature limitation in the instant claims is still deemed NEW MATTER. Additionally the page 16 disclosure of the specification that melt temperature is dependent on primer length, GC percentage, etc. also is not a disclosure of a limitation in the practice of the instant invention. These disclosures are information not guidance as to how to practice the claimed invention. Therefore, as originally filed, the limitation of using primers with similar melt temperatures was not disclosed making the addition of this limitation NEW MATTER. Applicants are advised that newly added disclosure is permitted in Continuation-in-part applications. The Examiner acknowledges that it may be reasonably speculated that primers should have similar melt temperatures as a limitation for the practice of the instant invention but that such speculation does not meet the requirement of a clear and concise enablement, as originally filed, as required under 35 U.S.C. § 112, first paragraph. The Examiner reiterates that a number of parameters are being manipulated as part of the disclosure to describe the operation of the instant invention and that there is no clear guidance as to whether similar primer melt temperatures may or may not be critical to the successful practice of the instantly claimed method. Since PCR reactions are performed normally with polymerization temperatures significantly below those of primers being used, a reasonable limitation that the polymerization temperature must be well below that of the melt temperature for the lowest melting primer is an

expected limitation on a method such as instantly claimed, but not that the primers must have similar melt temperatures. Lastly applicants assert that the fact that all of the primers of Table 1 have similar melt temperatures cannot be mere happenstance, in view of the importance of this disclosed relationship. This is an assertion that lacks factual support as to whether the melt temperatures are similar by happenstance. Secondly, applicants state the phrase "in view of the importance of this disclosed relationship". The Examiner wishes to point out that said "importance" was not disclosed in the originally filed application but only in subsequent amendments filed much after the original application filing date.

The limitation of claim 18 to a Tm spread of no more than 8.5 degrees C is also NEW MATTER. The specific melt temperatures given in Table 1 are just that, specific melt temperatures. There is no disclosure in the instant application, as filed, that a "range" such as within 8.5 degrees C is a limitation on the instant invention. Similarly the 4.5 degree C limitation of claim 19 is a range not supported by specific melt temperature disclosures.

Claims 1-8 and 18-20 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claim 20 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. This rejection is necessitated by the amendment newly adding claim 20.

The last three lines of claim 20 are vague and indefinite in that it is therein stated that "whether" amplified extension products have been synthesized is a measure of the presence or "amount" of each target sequence. It is unclear and confusing how the similar presence of amplified extension product cited by the word "whether" can be indicative of the "amount" of any target nucleic acid.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35

U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-8 and 18-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Kogan et al.

This rejection is maintained and reiterated as given in the previous office action mailed 3/10/92 and also applied to the newly added claims, necessitated by amendment, as they do not add nonobvious disclosure in view of their NEW MATTER content as summarized above.

Applicants argue that the balancing of the primer melt temperatures distinguishes the instant invention over Kogan et al. This is moot in overcoming this rejection because the NEW MATTER rejection based on said primer melt temperature balancing has been maintained as discussed above. Applicants discuss the importance of balanced primer melt temperatures with regard to the signals from the various primer sets in the cycles of PCR and state that the prior art does not teach or suggest this melt temperature limitation. The Examiner wishes to note that the instant application, as filed, does not teach or suggest this primer melt temperature balancing requirement either. Therefore this argument is deemed non-persuasive in overcoming this rejection based on 35 U.S.C. § 103.

Prior art made of record in the parent applications serial numbers 07/256,689 and 07/770,742 is hereby also made of official record as having been considered in the instant application.

No claim is allowed.

This is a file-wrapper-continuation of applicants' earlier

application S.N. 07/770,742. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See M.P.E.P. § 706.07(b). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application contains claims 9-17, drawn to an invention non-elected without traverse in Paper No. 7, filed 8/16/90. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. § 1.144) M.P.E.P. § 821.01.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The CM1 Fax Center number is (703) 305-3014 or (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

AM

A. MARSCHEL:am

May 27, 1994

M. Parr 5/30/94

MARGARET PARR
SUPERVISORY PATENT EXAMINER
GROUP 1800